Biomarker, Imaging, & QOL Studies Funding Program (BIQSFP)

'16 Study Checklist for Randomized Clinical Trials with a Comparator Arm and Cost-Effectiveness Analysis (CEA) Component

INSTRUCTIONS: Please submit a response to each of the criteria below and complete one Study Checklist for each biomarker endpoint. The Proposal Package must also include a budget at the time of submission that clearly details the Direct and Indirect costs of the requested funding. The budget for the project should use the standard PHS 398 budget form (http://grants.nih.gov/grants/funding/phs398/phs398.html) along with a narrative justifying each requested cost. The Budget packet must include a completed NIH biosketch form for each study PI. Form SF424 can be found at: http://grants.nih.gov/grants/funding/424/index.htm#format. Additional information on the new biosketch requirements can be found at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-024.html.

NOTE: CEA study applications must be submitted after parent concept approval but prior to protocol activation. Subsequent NCI prioritization and approval for funding will be decided by CTROC after evaluation of the study(s) by the respective NCI Steering Committee (SSC).

1. Explain why it is necessary to conduct this CEA alongside the parent clinical trial. For example, explain why an independent modeling study conducted during or after the clinical trial is completed is not feasible and/or why it would be of lesser value in informing clinical practice and/or policy compared to a CEA conducted alongside the parent clinical trial.

2. Describe and justify the perspective of the CEA.

3. Explain the situations in which the outcomes of the clinical trial could substantially change clinical practice.

4. Describe the potential implication(s) of different outcomes of the trial on overall costs to the health care system, in terms of costs saved or costs added.

5. Briefly describe and justify the CEA study in terms of:
   A. Trial population (in relationship to treatment population in community practice)
   B. Intervention(s) and control therapy selected for the CEA
   C. Question or hypothesis posed
   D. Measure(s) of outcome for the CEA
   E. Method of estimating costs
   F. Modeling approach proposed (if appropriate; e.g., decision tree, Markov, micro-simulation, etc. Provide sources of documentation if using an existing model. If a model is to be developed, the expertise of model developer, timeline for model development, calibration, and validation (if relevant) must be included in the proposal. This may include but not be limited to all model inputs that are needed and sources for these inputs, what provisions need to be made to document model structure, assumptions, data inputs, parameter estimation, intermediate and final outputs so that replication of the CEA would be possible by an external analyst.)
   G. Approach to characterizing uncertainty analysis
   H. The time horizon and discount rates of the CEA. If the time horizon of the CEA exceeds that of the trial, describe the extrapolation or modeling approach that will be used.

6. Describe all data elements that will be collected for the CEA. This description should include:
   A. A description of data elements that will already be collected as part of the protocol of the parent study and which additional data elements will need to collected.

B. A description of the data instrument development and validation process for new data elements.
C. A description of resources and personnel required for data collection and how the added data collection is consistent with the intended protocol of the parent study, (e.g., is it logistically feasible and will not create and unreasonable additional burden.
D. A description of any sources of data elements external to the parent protocol (e.g., linked or unlinked administrative data). If relevant describe external data sources and methods for obtaining estimates of unit cost. Provide information supporting whether unit cost estimates are relevant, consistent and valid.

7. Provide a power analysis to indicate that the sample sizes for health outcomes and economic data elements are sufficient to result in confidence intervals around the cost effectiveness ratio that render the results of the CEA useful to decision makers.

8. Describe any threats to the external validity of the study in relation to community practice.

3/10,3/11,3/12,1/13,11/13,12/14,12/15

Please complete and return to the appropriate CTEP/DCP PIO and Dr. Raymond Petryshyn at CCCT (petryshr@mail.nih.gov).

Thank you.